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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/798,470 | 03/11/2004 | Daniel H. Teitelbaum | UM-08764 | 7421 |
| 23535 | 7590 | 07/31/2007 | EXAMINER | |
| MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105 | | | SPIVACK, PHYLLIS G | |
| | | ART UNIT | PAPER NUMBER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/798,470 | TEITELBAUM ET AL. |
| | Examiner | Art Unit |
| | Phyllis G. Spivack | 1614 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 May 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4,7 and 18-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1-4 and 18-21 is/are allowed.

6) Claim(s) 7, 22 and 23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

Applicants' Amendment and Declaration of Daniel H. Teitelbaum, M.D. under 37 CFR 1.132, both filed May 11, 2007, are acknowledged. Claim 5 is canceled. Claims 1-4, 7 and 18-23 remain under consideration.

Applicants' arguments have been fully considered and are persuasive in part. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently applied to the instant claims.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

Claim 7 contains the trademark/trade name Servier S-5590. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an ACE inhibitor and, accordingly, the identification/description is indefinite.

Applicants are requested to show the structure and provide generic terminology for the compound as recited in claim 7.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodgers et al., U.S. Patent 6,821,953, in view of The Merck Index.

Rodgers teaches the administration of angiotensin converting enzyme (ACE) inhibitors along with a peptide fragment in various inflammatory conditions of the bowel, such as ulcerative colitis. See claim 11, as well as column 3, lines 4-25, where examples of angiotensin converting enzyme inhibitors are disclosed. The open language of the present claims allows for the inclusion of any number of additional active agents in the claimed methods. See column 9, lines 59-63. The claims differ in that Rodgers fails to describe a reduction in the characteristics that define an inflammatory bowel disease, such as histological parameters, the presence of heme positive stools, weight loss and clinical severity of colitis. However, the qualitative and quantitative determinations of such characteristics are conventionally examined when a practitioner skilled in the art of gastroenterology ascertains the progression of an inflammatory bowel disease. The **Inflammatory Bowel Diseases** section of the The Merck Index establishes that weight loss, histological parameters, heme positive stools and clinical symptoms are routinely followed in patients having inflammatory bowel diseases. See, in particular, the sections describing Pathology and Symptoms, Signs

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and Complications. A reference may be applied for all it teaches or suggests to one of ordinary skill in the gastroenterology art. In view of the combined teachings of Rodgers and The Merck Index, it would have been reasonable to expect a reduction in the severity of an inflammatory bowel disease following the administration of an ACE inhibitor, optionally in combination with another active agent.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acton et al., U.S. Patent 6,632,830, in view of The Merck Index.

Acton teaches the administration of an angiotensin converting enzyme (ACE) inhibitor in the treatment of an inflammatory bowel disease. See column 36, lines 60-61, as well as column 37, lines 12-23. The claims differ in that Acton fails to describe a reduction in the characteristics that define an inflammatory bowel disease, such as histological parameters, the presence of heme positive stools, weight loss and clinical severity of colitis. However, the qualitative and quantitative determinations of such characteristics are conventionally examined when a practitioner skilled in the art of gastroenterology ascertains the progression of an inflammatory bowel disease. The **Inflammatory Bowel Diseases** section of the The Merck Index establishes that weight loss, histological parameters, heme positive stools and clinical symptoms are routinely followed in patients having inflammatory bowel diseases. See, in particular, the sections describing Pathology and Symptoms, Signs and Complications. A reference may be applied for all it teaches or suggests to one of ordinary skill in the gastroenterology art. In view of the combined teachings of Acton and The Merck Index,

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it would have been reasonable to expect a reduction in the severity of an inflammatory bowel disease following the administration of an ACE inhibitor.

Dr. Teitelbaum states in his Declaration that ACE-inhibition is complex, not intuitive in nature and specific to targeted areas of a mammalian organism. Descriptions of mechanisms of ACE inhibition are set forth with apparent support from various publications that are not presently of record in the instant application. Further, Dr. Teitelbaum urges the use of ACE-inhibitors as a treatment for inflammatory bowel disease is "refuted by the numerous publications in the literature that show that a tissue or human's response to ACE-inhibitors may be distinctly different and completely unpredictable."

It is noted no such publications are provided.

With respect to the Rodger et al., U.S. Patent 6,821,953, and the Acton et al., U.S. Patent 6,632,832, references, Dr. Teitelbaum argues they do not provide substantiation or documented specific experiments to support the suppositions that inflammatory bowel disease might benefit via treatment with an ACE-inhibitor. It is further asserted the other compounds (in addition to amino acid peptide fragments) listed in Rodgers, i.e., anti-inflammatory drugs, ACE-inhibitors, anti-infectives, growth factors and antihistamines, characterized as "a very broad group," arbitrarily provide agents that may have anti-inflammatory properties under some conditions.

It is noted in the last paragraph on page 8 of the present specification that the instant ACE inhibitors may be contained in compositions with one or more compounds or agents including, but not limited to, other ACE inhibitors, other therapeutic agents,

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physiologically tolerable liquids, gels, carriers, diluents, adjuvants, excipients, salicylates, steroids, immunosuppressants, antibodies, cytokines, antibiotics, binders, fillers, preservatives, stabilizing agents, emulsifiers and buffers. Accordingly, the list of additional agents reflects "a very broad group" that may have anti-inflammatory properties under some conditions.

Further, Applicants urge the references applied in the art rejections of record do not teach or describe that an ACE inhibitor can alter weight loss, histological parameters, onset of heme positive stool and clinical symptoms of colitis when administered to a subject with inflammatory bowel disease. Applicants state there is no reasonable expectation of success because there is no way to predict whether an ACE inhibitor could be used to achieve a reduction in the severity of inflammatory bowel disease, particularly in view of the possibility that ACE-inhibitor administration may result in inflammation. (No support is provided.)

Applicants' arguments fail to persuade the Examiner of an error in setting forth the rejections of record under 35 U.S.C. 103. Providing a subject with inflammatory bowel disease to whom a therapeutic composition comprising an angiotensin converting enzyme inhibitor is administered is clearly taught by both Rodgers and Acton. Both Rodgers and Acton meet the requirement of a specific patient population, i.e., those having inflammatory bowel disease, and the requirement of administration of specific therapeutic agents, i.e., ACE inhibitors. The elucidation of the inherent mechanisms of action of ACE-inhibition in the treatment of inflammatory bowel disease, while

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meritorious, is not herein at issue. The open language of the present claims allows for the inclusion of any number of additional active agents in the claimed methods.

In view of the teachings of the The Merck Index, one skilled in the gastroenterology art would have been motivated to monitor weight loss, histological parameters, potential heme positive stools and clinical symptoms that represent the symptoms, signs and complications of the course of an inflammatory bowel disease. As required by instant claims 22 and 23, such clinical parameters are recognized in the art to indicate a reduction in the severity of inflammatory bowel disease. The administration of "other compounds" is not recited in claims 22 and 23.

Thus, in view of a finding of a recognized problem, a predictable potential solution and a reasonable expectation of success, an accepted standard for ascertaining obviousness is presented.

Claims 1-4, 7 and 18-21 appear to be free of the art.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 28, 2007

Phyllis Spivack

PHYLIS SPIVACK
PRIMARY EXAMINER

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